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10/501,110	12/02/2004	Shiroo Muraoka	61625 (70232)	1701
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EDWARDS ANGELI, PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			JUNG, UNSU	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,110	<b>Applicant(s)</b> MURAOKA ET AL.
	<b>Examiner</b> UNSU JUNG	<b>Art Unit</b> 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 August 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,5,8 and 11 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,5,8 and 11 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 08 July 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. Applicant's amendments in the reply filed on August 11, 2009 have been acknowledged and entered. The reply included amendments to claims 1 and 8 and cancellation of claims 3, 6, 7, 9, 10, 12, and 14-17.

***Status of Claims***

2. Claims 1, 5, 8, and 11 are pending and currently under consideration for patentability under 37 CFR 1.104.

***Priority***

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The instant application is a national phase application filed under 35 U.S.C. §371 from PCT Application No. PCT/JP2004/002604, filed on March 3, 2004, which claims priority to Japanese Patent Application No. JP 2003-340412, filed on September 30, 2003

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Japanese Patent Application No. JP 2003-340412 has been filed in the instant application.

***Rejections Withdrawn***

4. The following rejections have been withdrawn in view of amended claim 1 and canceled claims 3, 6, 7, 9, 10, 12, and 14-17 in the reply filed on September 29, 2008:

- Rejection of claims 12 and 14-17 under 35 U.S.C. 112, second paragraph;
- Rejection of claims 12 and 14-17 under 35 U.S.C. 102(a) and 102(e) as being anticipated by Yeung et al. (U.S. PG Pub. No. US 2003/0044869 A1, published Mar. 6, 2003 and filed Sept. 4, 2001);
- Rejection of claims 1, 3, 5, and 6-8 under 35 U.S.C. 103(a) as being unpatentable over Knowles et al. (U.S. Patent No. 4,658,022, Apr. 14, 1987) in view of Macri et al. (*Electrophoresis*, 2000, Vol. 21, pp1685-1693);
- Rejection of claims 9 and 10 under 35 U.S.C. 103(a) as being unpatentable over Knowles et al. (U.S. Patent No. 4,658,022, Apr. 14, 1987) view of Macri et al. (*Electrophoresis*, 2000, Vol. 21, pp1685-1693), and further in view of Winkler et al. (U.S. Patent No. 5,645,838, July 8, 1997); and
- Rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Knowles et al. (U.S. Patent No. 4,658,022, Apr. 14, 1987) view of Macri et al. (*Electrophoresis*, 2000, Vol. 21, pp1685-1693), and further in view of Yeung et al. (U.S. PG Pub. No. US 2003/0044869 A1, published Mar. 6, 2003 and filed Sept. 4, 2001).

***New Grounds of Rejections***

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowles et al. (U.S. Patent No. 4,658,022, Apr. 14, 1987) (hereinafter "Knowles") in view of Macri et al. (*Electrophoresis*, 2000, Vol. 21, pp1685-1693) (hereinafter "Macri") and Winkler et al. (U.S. Patent No. 5,645,838, July 8, 1997) (hereinafter "Winkler").

With respect to claims 1 and 5, Knowles teaches an immunoassay for detecting a water-sparingly-soluble/hardly extractable protein in a sample. The method involves immunizing an animal against an immunogen comprising a protein solubilized with an aqueous ionic surfactant such as sodium dodecyl sulfate (SDS) (column 9, lines 56-60, "immunizing a desired host animal with a suitably denatured form of a protein"; and column 8, line 15) and raising antibodies against the solubilized protein (column 9, lines 56-60, "examine the resulting immune response for antibodies exhibiting the desired increased specificity and/or avidity"; column 3, lines 14-18, "somatic cell hybridization techniques to obtain antibodies"). This method reads on the claimed step (1) of extracting and/or solubilizing a water-sparingly-soluble/hardly extractable protein in a sample with an aqueous solvent containing an ionic surfactant such as SDS to provide a protein solution. The immunizing step of Knowles reads on the claimed step (2) of providing an immunogen for raising an antibody, against the water-sparingly-soluble/hardly extractable protein to be detected, wherein the immunogen is prepared by dissolving the water-sparingly-soluble/hardly extractable protein in an aqueous solvent containing the same ionic surfactant as that contained in the aqueous solvent of

step (1) and claimed step (3) of preparing the antibody against the water-sparingly-soluble/hardly extractable protein to be detected by immunizing an animal with the immunogen provided in step (2) and obtaining the antibody from the immunized animal.

Knowles further teaches a detection method, in which antibodies raised against the protein are added to the solubilized protein sample for determining binding of the antibody reagent to the protein (column 10, lines 17-18). Such detection method of Knowles reads on the claimed step (4) of adding the antibody to the protein solution of step (1) or a dilution of the protein solution of step (1) to form a reaction mixture, the claimed step (5) of incubating the reaction mixture of step (4) to form an antigen-antibody complex between the water-sparingly-soluble/hardly extractable protein and the antibody in the presence of ionic surfactant contained the aqueous solvent of step (1), and the claimed step (6) of detecting the formed antigen-antibody complex.

Knowles teaches that the aqueous solvent in step (1) further comprises a reducing agent of 2-mercaptoethanol (column 8, line 23).

However, Knowles fails to teach a method, wherein the concentration of ionic surfactant in the aqueous solvent is higher than 0.3% w/v. Knowles further fails to teach an additional step of boiling the protein solution for 50 minutes at the temperature of at least 80°C.

Macri teaches membrane protein solubilization method, in which SDS is used at 4% w/v (see entire document, particularly p1687, *2.2.4 Protein solubilization of SR and SL fractions*), which reads on the claimed range of greater than 0.03% w/v.

Winkler teaches a method of solubilizing membrane protein by adding SDS boiling the solution for 5 minutes (see entire document, particularly columns 12-13, Example 6).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art the time of the invention to employ the solubilization method of Macri, in which SDS is used at 4% w/v, in the method of Knowles in order to solubilize membrane proteins. One skilled in the art would have been motivated to employ a concentration of surfactant well known in the membrane protein chemistry arts in order to solubilize the membrane protein with a reasonable expectation of success.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the concentration of ionic surfactant such as SDS in the aqueous solvent as greater than 0.03% w/v, greater than 0.3% w/v, or 1% w/v as currently recited in claims 1, 3, and 8, since it has been held that that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable ranges involves only routine skill in the art absent unexpected results. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382; *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the denaturing/solubilizing method of Winkler in

the method of Knowles in view of Macri in order to solubilize membrane proteins for further biochemical analysis. The advantage of adding an additional step, which further solubilizing the membrane proteins, provides the motivation to combine teachings of Knowles in view of Macri and Winkler with a reasonable expectation of success.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to select an appropriate boiling temperature such as 80°C as recited in instant claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable ranges involves only routine skill in the art absent unexpected results. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382; *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knowles (U.S. Patent No. 4,658,022, Apr. 14, 1987) view of Macri (*Electrophoresis*, 2000, Vol. 21, pp1685-1693) and Winkler (U.S. Patent No. 5,645,838, July 8, 1997) as applied to claim 1 above, and further in view of Yeung et al. (U.S. PG Pub. No. US 2003/0044869 A1, published Mar. 6, 2003 and filed Sept. 4, 2001) (hereinafter "Yeung").

Knowles in view of Macri teaches an immunoassay for detecting the presence of a water-sparingly-soluble/hardly extractable protein in a sample as set forth above.

However, Knowles in view of Macri fails to teach a method, wherein the protein is a peanut protein.

Yeung teaches a method and a kit for the presence of a protein in a sample as set forth above.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the method of Knowles in view of Macri to detect peanut proteins of Yeung since peanut proteins can be detected for food contamination testing purpose in food industry. The advantage of detecting an important food allergen in food industry provides the motivation to combine teachings of Knowles in view of Macri and Yeung with a reasonable expectation of success.

#### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1, 5, 8, and 11 have been considered but are moot in view of the new ground(s) of rejection. However, the applicant's arguments regarding the rejection of claims 9 and 10 under 35 U.S.C. 103 as being unpatentable over Knowles in view of Macri and Winkler have been addressed as they also apply to the current grounds of rejections.

Applicant's argument that Winkler does not teach that the boiling step can be performed prior to the immune reaction has been fully considered but is not found persuasive essentially for the reasons of record. As acknowledged by the applicant, the solubilization of membrane proteins as taught by Winkler involves affinity separation involving protein A Sepharose treatment followed by a boiling procedure. This process

is performed in order to acquire soluble form of membrane proteins, which can be used for subsequent biochemical assays. Although Winkler does not specifically teach that immuno assays are performed following the membrane protein solubilization process, Winkler does not teach away from performing such assays. A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). General skepticism of those in the art -- not amounting to teaching away -- is also "relevant and persuasive evidence" of nonobviousness. Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 726, 16 USPQ2d 1923, 1929 (Fed. Cir. 1990). In effect, "teaching away" is a more pointed and probative form of skepticism expressed in the prior art. In any case, the presence of either of these indicia gives insight into the question of obviousness.

In this case, Knowles teaches a method of using solubilized membrane proteins in an immune assay (column 3, lines 14-18, "somatic cell hybridization techniques to obtain antibodies") as set forth in the previous Office Action dated May 12, 2009 (see item 14). The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. at \_\_\_, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ

449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950). “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396. Given the membrane protein solubilization method is known in the art as taught by Winkler, one skilled in the art could have combined the known solubilization method such as that of Winkler in the method of Knowles without change in the function of solubilizing membrane proteins for further biochemical assays and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art.

In view of the foregoing response to arguments, the prior art rejections under 35 U.S.C. 103(a) set forth in the current Office Action have been maintained.

Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

### ***Conclusion***

11. No claim is allowed.
  
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1641